



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

November 8, 2022

Heather Bjornson-Lam  
Authorized Representative  
Veltek Associates, Inc.  
15 Lee Boulevard  
Malvern, Pennsylvania 19355  
Electronic Transmittal: heather.bjornson@sterile.com

Subject: PRIA Label Amendment – Addition of Sporicidal Claims  
Product Name: HYPO-CHLOR Neutral 0.52%  
EPA Registration Number: 68959-9  
Received Date: 9/30/2021  
Action Case Number: 00327768

Dear Ms. Bjornson-Lam:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. Pursuant to 40 CFR 156.10(a)(6), you must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process, FIFRA section 12(a)(1)(B). Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Assurance.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Melanie Bolden by phone at (202) 566-0674, or via email at [Bolden.Melanie@epa.gov](mailto:Bolden.Melanie@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read 'D. Fuller', with a long horizontal stroke extending to the right.

Demson Fuller, Product Manager 32  
Regulatory Management Branch I  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

Enclosure



{Front Panel}

**HYPO-CHLOR® NEUTRAL 0.52%**  
**For Use in Cleanrooms and Controlled Areas**  
**Hard Surface [Hospital] [Broad Spectrum] Disinfectant**

**Germicide**

**\*Virucide**

**Fungicide**

[Aseptically Filtered at 0.2 µm] [Sterile]

[Ready to Use After Mixing]

Sterile Pharmaceutical Clean Room Formula

Filtered at 0.2 µm and Aseptically Filled into Presterilized Components

**ACCEPTED**

Nov 08, 2022

Under the Federal Insecticide, Fungicide  
and Rodenticide Act as amended, for the  
pesticide registered under  
EPA Reg. No. 68959-9

[Sodium Hypochlorite at 0.52% [w/w] [in] [which includes] [formulated with] USP Water  
for Injection Quality Water (0.52 EU/mL)]

**Active Ingredient:**

\*\*Sodium Hypochlorite CAS# 7681-52-9..... 0.52%

**Other Ingredients:**.....99.48%

Total .....100.00%

\*\*After mixing a decrease in % of active ingredient is expected., use within (24 hours) (7 days)  
or discard any unused material.

**KEEP OUT OF REACH OF CHILDREN**  
**WARNING**

*{Note to reviewer: The following reference statements available for various packaging  
scenarios.}*

[See [side] [other] [back] [case label] [panel] [and/or] [package insert] for [first aid] [precautionary  
statements] [directions for use] [additional precautions] [and] additional product information].]

[Refer to the primary case label for [additional] precautionary statements, directions for use, and  
additional product information]

[Peel [here] [back] for [Spanish and] additional information]

[See container for lot number and storage expiration date]

{Lot Label Sticker}

Reorder {xxxxxxxxxxxxx}

{QR Code}

Lot: {xxxxxxx}

EXP. {dd-MM-YYYY}

Net Contents: {(XXX mL /L) on Container or on Case (XX/CASE, Container size (yyy))}

Rev. M#/YY ●{code}



Patents: [www.sterile.com/patents](http://www.sterile.com/patents)

**Net Contents:** (XX oz or gallons)

**EPA Reg. No.:** 68959-9

**EPA Est. No.:** For EPA Est. No. see the final character of the lot #: L = 68959 –PA-01, C = 68959-PA-03, T = 68959-PA-02

**Manufactured by:**

Veltek Associates, Inc.  
15 Lee Blvd., Malvern PA 19355 – 1234 USA  
Tel: 610-644-8335  
[www.sterile.com](http://www.sterile.com)

**Made in USA**

**VAI** {corporate logo}

{End of Front Panel}

{Side/Back Panel}

**FIRST AID**

**If in Eyes:**

If splashed in eyes, hold eye open and rinse slowly and gently with water for 15-20 minutes, Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

**If on Skin or Clothing:**

Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

**If Inhaled:**

Move person to fresh air. If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

**If Swallowed:**

Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.

**EMERGENCIES:** In the case of emergency call: 1-866-928-0789 (toll free) or 1-215-207-0061



## **PRECAUTIONARY STATEMENTS**

### **HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**WARNING.** Causes substantial but temporary eye injury. Causes skin irritation. Harmful if inhaled. Do not breathe spray mist. Do not get into eyes, on skin, or on clothing. Wear protective eye wear (goggles, face shield, or safety glasses), long-sleeved shirt and long pants, socks, shoes, and waterproof or chemical-resistant gloves. Wash thoroughly with soap and water after handling and before eating., drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

**ENVIRONMENTAL HAZARDS:** Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

**PHYSICAL AND CHEMICAL HAZARDS:** Contact with acid releases toxic chlorine gas. Do not mix this product with other chemicals.

## **DIRECTIONS FOR USE**

**Read the label before using.**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product is not for use on medical devices.

**LOCATIONS OF USE:** Disinfects cleanrooms and controlled areas such as those in hospitals and health care institutions, and biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing, cosmetic manufacturing, and lab animal facilities. Use on hard non-porous, inanimate, surfaces in aseptic filling and gowning rooms, general manufacturing areas and laboratories or on: machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves, made of plastic, Plexiglas®, glass, vinyl, glazed porcelain, laminates, glazed tile, and stainless steel. It is compatible with most hard non-porous surface materials. Not for use on food contact surfaces.

**PREPARE USE SOLUTION:** Follow SimpleMix System Container instructions.

### **SimpleMix System Container Instructions:**

{On (16 Ounce) Trigger Spray Bottle label}

*Trigger Spray Bottle* [label]:

1. To prepare use solution, open cap.
2. Peel off inner seal by grasping tab at far edge and pulling off.
3. Firmly push small, inner container [(completely) (all the way)] down.
4. Replace cap and tighten.
5. Slowly swirl for 15 seconds.
6. Move spray nozzle to open position.
7. Follow directions for use on label.



{On 1 Gallon Size Bottle label}

*Gallon Size Bottle* [label]:

1. To prepare use solution, open cap.
2. Peel off inner seal by grasping tab at far edge and pulling off.
3. Firmly push small, inner container [(completely) (all the way)] down.
4. Replace cap and tighten.
5. Slowly swirl for 15 seconds.
6. Open small side spout and peel off inner seal, as above.
7. Pour solution from small side spout onto surfaces to be treated or alternate containers.
8. Follow directions for use on label.

{On 55 Gallon (200 L) Drum label. Note to reviewer: to be used with customer supplied pump}

55 Gallon (200 L) Drum [label]:

1. Close all valves
2. Uncoil hoses.
3. Connect center hose to pump between X and Y.
4. Open valve 1, then valve 2, then valve 4.
5. START pump to empty cubic container.
6. When cubic container is empty, turn pump OFF.
7. Close valve 1 and valve 2.
8. Open valve 6 and valve 5.
9. Re-start pump and mix 15 minutes.
10. STOP pump.
11. Close valve 4.
12. To dispense – Open Valves 3 and 7. Run pump only when dispensing.
13. Follow directions for use on the label.

### **FOR THE FOLLOWING USES, MIX AND USE WITHIN 7 DAYS**

**SPORICIDAL:** HYPO-CHLOR Neutral 0.52 % is an effective sporicide against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584) on non-porous hard surfaces in 90 minutes. Pre-clean all surfaces. Thoroughly wet surface by immersion or by flooding with the prepared use solution and allow (surface) (item) to soak or remain visibly wet for a minimum of 90 minutes. Allow surface to air dry, or after 90 minutes rinse and wipe dry with sterilized cloth wiper, if desired. After mixing, use or discard within 7 days.

**DISINFECTION:** HYPO-CHLOR Neutral 0.52% is an effective hard surface [(hospital)] disinfectant on inanimate, non-porous, non-food contact surfaces as demonstrated in testing against *Pseudomonas aeruginosa* (ATCC# 15442), and *Staphylococcus aureus* (ATCC#6538) in 10 minutes. Pre-clean all surfaces. Thoroughly wet surface with the prepared use solution and allow to remain wet for a minimum of 10 minutes. Allow surface to air dry, or after 10 minutes rinse and wipe dry with sterilized cloth wiper, if desired. After mixing, use or discard



within 7 days. {Note to reviewer: This paragraph will not be present on a market label with the 24 hour disinfection DFU}

**FUNGICIDAL:** HYPO-CHLOR Neutral 0.52% is an effective fungicide on inanimate, non-porous non-food contact surfaces, demonstrated by the results of AOAC Efficacy Tests against *Trichophyton interdigitale* (ATCC# 9533) in 10 minutes. Pre-clean all surfaces. Thoroughly wet surface with the prepared use solution and allow to remain wet for a minimum of 10 minutes. Allow surface to air dry, or after 10 minutes, rinse and wipe dry with sterilized cloth wiper, if desired. After mixing, use or discard within 7 days. {Note to reviewer: This paragraph will not be present on a market label with the 24 hour fungicidal DFU}

#### **FOR THE FOLLOWING USES, MIX AND USE WITHIN 24 HOURS**

**DISINFECTION:** HYPO-CHLOR Neutral 0.52% is an effective hard surface [(hospital)] disinfectant on inanimate, non-porous non-food contact surfaces demonstrated in testing against *Pseudomonas aeruginosa* (ATCC# 15442), and *Staphylococcus aureus* (ATCC#6538) in 5 minutes. Pre-clean visibly soiled surfaces. Thoroughly wet surface with the prepared use solution and allow to remain wet for a minimum of 5 minutes. Allow surface to air dry, or after 5 minutes rinse and wipe dry with sterilized cloth wiper, if desired. After mixing, use or discard within 24 hours. {Note to reviewer: This paragraph will not be present on a market label with the 7 day disinfection DFU}

**FUNGICIDAL:** HYPO-CHLOR Neutral 0.52% is an effective fungicide on inanimate, non-porous non-food contact surfaces, demonstrated by the results of AOAC Efficacy Tests against *Trichophyton interdigitale* (ATCC# 9533) in 5 minutes. Pre-clean visibly soiled surfaces. Thoroughly wet surface with the prepared use solution and allow to remain wet for a minimum of 5 minutes. Allow surface to air dry, or after 5 minutes, rinse and wipe dry with sterilized cloth wiper, if desired. After mixing, use or discard within 24 hours. {Note to reviewer: This paragraph will not be present on a market label with the 7 day fungicidal DFU}

**\*VIRUCIDAL:** The results of AOAC Efficacy Tests show that HYPO-CHLOR Neutral 0.52% is an effective virucide on inanimate, non-porous, non-food contact surfaces, demonstrated in testing against \*Human Adenovirus 5 (ATCC# VR-5), \*Influenza A Virus, H3N2 (ATCC# VR-1679), and \*Poliovirus Type 1(ATCC# VR-1562) in 5 minutes. Pre-clean visibly soiled surfaces. Thoroughly wet surface with the prepared use solution and allow to remain wet for a minimum of 5 minutes. Allow surface to air dry, or after 5 minutes rinse and wipe dry with sterilized cloth wiper, if desired. After mixing, use or discard within 24 hours.

**SANITIZATION OF NON-FOOD CONTACT SURFACES:** (not for use in California) HYPO-CHLOR Neutral 0.52% is an effective sanitizer on inanimate, non-porous non-food contact



surfaces demonstrated in testing against *Staphylococcus aureus* (ATCC#6538) and *Klebsiella pneumoniae* (ATCC#4352) in 5 minutes. Pre-clean visibly soiled surfaces. Thoroughly wet surface with the prepared use solution and allow to remain wet for a minimum of 5 minutes.

Allow surface to air dry, or after 5 minutes, rinse and wipe dry with sterilized cloth wiper, if desired. After mixing, use or discard within 24 hours.

### Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

**Storage:** Store in original container in a cool dry area away from direct sunlight and heat to avoid deterioration. In case of spill, flood area with large quantities of water.

**Disposal:** Product or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer. Follow Federal/Provincial/State regulations and Local/Municipal ordinances when disposing of this product. Improper disposal of excess product, spray mixture or rinsate is a violation of Federal/Provincial/State Laws. If these wastes cannot be disposed of by use according to label instructions, contact your Federal/Provincial/State or Local/Municipal environmental control agency for guidance.

**Container Handling:** *(Note to reviewer: This product is not dilutable.)*

Non-refillable container. Do not reuse or refill this container to hold materials other than this product. [(For containers equal to or less than 5 gallons) Offer container for recycling if available and dispose of in a sanitary landfill, or by incineration.] or [(For containers greater than 5 gallons) Offer container for recycling if available, or reconditioning if appropriate, or dispose of in a sanitary landfill, or by incineration.].

{Note: To appear as label end panel for customer use on containers: convenience item.}

User Information
Date Opened/Operator:
<input type="text"/>
Expiration Date:
<input type="text"/>
Area:
<input type="text"/>



*(Note to reviewer: Optional Visual to Ensure Customer Compliance with Directions)*

**{1 Gallon SimpleMix}**



**{16 Ounces SimpleMix}**



**(Logo)**





### Optional Label Claims

- HYPO-CHLOR Neutral 0.52% has been developed for use in cleaning rotation cycles where hard surface disinfectants are essential for reducing cross-contamination.
- HYPO-CHLOR Neutral 0.52% has been formulated as a sterile pharmaceutical cleanroom formula.
- Sterile pharmaceutical cleanroom formula.
- HYPO-CHLOR Neutral 0.52% disinfects as it cleans in one operation.
- HYPO-CHLOR Neutral 0.52% is a registered sporicide, disinfectant, and fungicide for use in areas where housekeeping and controlling cross-contamination is of prime importance.
- When used as directed, HYPO-CHLOR Neutral 0.52% is effective against a broad spectrum of pathogenic microorganisms including spore forming bacteria, *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584) on non-porous, hard surfaces in 90 minutes, when used within 7 days after mixing.
- When used as directed, HYPO-CHLOR Neutral 0.52% is an effective virucide on inanimate, non-porous, non-food contact surfaces, in the presence of organic load (5% Bovine Serum), demonstrated in testing against \*Human Adenovirus 5 (ATCC# VR-5), \*Influenza A Virus H3N2(ATCC# VR-1679), and \*Poliovirus Type 1(ATCC# VR-1562) in 5 minutes.
- When used as directed, HYPO-CHLOR Neutral 0.52% is an effective sanitizer on inanimate, non-porous non-food contact surfaces demonstrated in testing against *Staphylococcus aureus* (ATCC#6538) and *Klebsiella pneumoniae* (ATCC#4352) in 5 minutes.
- When mixed and used within 7 days, HYPO-CHLOR Neutral 0.52% is an effective sporicide, disinfectant, and fungicide.
- When mixed and used within 24 hours, HYPO-CHLOR Neutral 0.52% is an effective sporicide, disinfectant, virucide, (and) fungicide (,and non-food contact sanitizer).



- HYPO-CHLOR® Neutral 0.52% is available in our convenient, ready-to-use, SimpleMix System.
- HYPO-CHLOR® Neutral 0.52% has been designed for [(pharmaceutical) (medical device) (biopharmaceutical) (biotechnology) (healthcare) (lab animal) facilities that demand a neutral pH sodium hypochlorite solution adequate for maintaining a clean and critical environment.
- Made in the USA.
- This neutralized solution can be used as a sodium hypochlorite cleaner on numerous cleanroom surfaces with reduced consequences of corrosion, pitting, and rusting.



### Emerging Viral Pathogens

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large Non-Enveloped Viruses

For an emerging viral pathogen that is a/an	...follow directions for use for the following organisms on the label
Enveloped virus	Poliovirus Type 1 (ATCC VR-1562)
Large, non-enveloped virus	Poliovirus Type 1 (ATCC VR-1562)

Acceptable claim language:

[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, [product name] can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name emerging virus]. [Product name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.